

17

the primary-lead electrodes is switched so that all of the primary-lead electrodes are commonly charged. The secondary-lead electrode **35** is then charged so that its polarity is opposite that of the primary-lead electrodes **34**. Where the primary electrodes **34** and the secondary electrode **35** are spaced sufficiently close together, when the vein wall collapses around the primary lead electrodes, the electrode at the distal end of the secondary lead can also come into contact with a portion of the vein wall so that an RF field is created between the primary electrodes **34** and the secondary electrode **35**.

The catheter **10** is pulled back to ensure apposition between the electrodes at the distal ends of the leads and the vein wall. When the catheter **10** is being pulled back, the primary-lead electrodes **34** remain in apposition with the vein wall **54** while the secondary-lead electrode **35** comes in contact with the portion of the vein wall previously collapsed by the primary-lead electrodes **34**. RF energy passes through the venous tissue between the primary-lead electrodes **34** and the secondary-lead electrode **35**. Ligation as the catheter is being retracted produces a lengthy occlusion which is stronger and less susceptible to recanalization than an acute point occlusion.

In a monopolar operation, the secondary-lead electrode **35** remains neutral, while the primary leads **30** are commonly charged and act in conjunction with an independent electrical device, such as a large low-impedance return pad (not shown) placed in external contact with the body, to form RF fields substantially evenly spaced around the circumference of the vein. The thermal effect produced by those RF fields along the axial length of the vein wall causes the vein wall to collapse around the primary-lead electrodes. Upon collapse of the vein wall, the secondary-lead electrode is charged to have the same polarity as that of the primary-lead electrodes. The electrode device is retracted as described in the bipolar operation.

In either bipolar or monopolar operation the application of RF energy is substantially symmetrically distributed through the vein wall. As previously described, the electrodes should be spaced no more than 4 or 5 millimeters apart along the circumference of the vein, which defines the target vein diameter for a designed electrode catheter. Where the electrodes are substantially evenly spaced in a substantially symmetrical arrangement, and the spacing between the electrodes is maintained, a symmetrical distribution of RF energy increases the predictability and uniformity of the shrinkage and the strength of the occlusion.

As shown in FIG. **14**, after the electrodes **34** come into apposition with the vein wall (FIG. **12**), and before the energy is applied to ligate the vein (FIG. **13**), an external tourniquet, such as an elastic compressive wrap or an inflatable bladder with a window transparent to ultrasound, is used to compress the anatomy, such as a leg, surrounding the structure to reduce the diameter of the vein. Although the compressive force being applied by the tourniquet may effectively ligate the vein, or otherwise occlude the vein by flattening the vein, for certain veins, this compressive force will not fully occlude the vein. A fixed diameter electrode catheter in this instance would not be effective. The electrodes **34** which are expanded outward by the formed leads **30** can accommodate this situation.

The reduction in vein diameter assists in pre-shaping the vein to prepare the vein to be molded to a ligated state. The use of an external tourniquet also exsanguinates the vein and blood is forced away from the treatment site. Coagulation of blood during treatment can be avoided by this procedure. Energy is applied from the electrodes to the exsanguinated

18

vein, and the vein is molded to a sufficiently reduced diameter to achieve ligation. The external tourniquet can remain in place to facilitate healing.

The catheter can be pulled back during the application of RF energy to ligate an extensive section of a vein. In doing so, instead of a single point where the diameter of the vein has been reduced, an extensive section of the vein has been painted by the RF energy from the catheter. Retracting the catheter in this manner produces a lengthy occlusion which is less susceptible to recanalization. The combined use of the primary and secondary electrodes can effectively produce a reduced diameter along an extensive length of the vein. The catheter can be moved while the tourniquet is compressing the vein, or after the tourniquet is removed.

Where the catheter includes a fluid delivery lumen, fluid can be delivered to the vein before RF energy is applied to the vein. The delivered fluid displaces blood from the treatment site to ensure that blood is not present at the treatment site, even after the tourniquet compresses the vein.

Where the tourniquet is an inflatable bladder with a window transparent to ultrasound, an ultrasound transducer is used to monitor the flattening or reduction of the vein diameter from the compressive force being applied by the inflating bladder. The window can be formed from polyurethane, or a stand-off of gel contained between a polyurethane pouch. A gel can be applied to the window to facilitate ultrasound imaging of the vein by the transducer. Ultrasound visualization through the window allows the operator to locate the desired venous treatment area, and to determine when the vein has been effectively ligated or occluded. Ultrasound visualization assists in monitoring any pre-shaping of the vein in preparation of being molded into a ligated state by the thermal effect produced by the RF energy from the electrodes.

After completing the procedure for a selected venous section, the actuator causes the leads **30** to return to the interior of the outer sheath **12**. Once the leads **30** are within the outer sheath **12**, the catheter **10** may be moved to another venous section where the ligation process is repeated.

The description of the component parts discussed above are for a catheter to be used in a vein ranging in size from 2 mm (0.08 in) to 10 mm (0.4 in) in diameter. It is to be understood that these dimensions do not limit the scope of the invention and are merely exemplary in nature. The dimensions of the component parts may be changed to configure a catheter **10** that may be used in various-sized veins or other anatomical structures.

Although described above as positively charged, negatively charged, or as a positive conductor or negative conductor, these terms are used for purposes of illustration only. These terms are generally meant to refer to different electrode potentials and are not meant to indicate that any particular voltage is positive or negative. Furthermore, other types of energy such as light energy from fiber optics can be used to create a thermal effect in the hollow anatomical structure undergoing treatment.

While several particular forms of the invention have been illustrated and described, it will be apparent that various modifications can be made without departing from the spirit and scope of the invention. Accordingly, it is not intended that the invention be limited, except as by the appended claims.

What is claimed is:

1. A method of treating a vein, the method comprising:
 - introducing an elongate energy delivery device into a vein having an inner wall;
 - pre-shaping the vein by moving the inner wall of the vein toward a distal portion of the energy delivery device, independently of the energy delivery device;